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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/673,167	09/30/2003	Lloyd Marks	117622-00102	9810
27557	7590	08/10/2006	EXAMINER	
BLANK ROME LLP 600 NEW HAMPSHIRE AVENUE, N.W. WASHINGTON, DC 20037			TOTH, KAREN E	
			ART UNIT	PAPER NUMBER
			3735	

DATE MAILED: 08/10/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

## Office Action Summary

Application No.

10/673,167

**Applicant(s)**

MARKS ET AL.

**Examiner**

**Karen E. Toth**

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**-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --**

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☒ Responsive to communication(s) filed on 13 July 2006.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 1-55 is/are pending in the application.  
4a) Of the above claim(s) 1-23 and 28-55 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☐ Claim(s) \_\_\_\_\_ is/are rejected.
- 7) ☒ Claim(s) 24-27 is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- 1) ☒ Notice of References Cited (PTO-892)  
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)  
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  
Paper No(s)/Mail Date 05/06/05.
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_.  
5) ☐ Notice of Informal Patent Application (PTO-152)  
6) ☐ Other: \_\_\_\_\_.

## DETAILED ACTION

### *Election/Restrictions*

1. Applicant's election with traverse of species VII in the reply filed on 13 July 2006 is acknowledged. The traversal is on the ground(s) that an election of species is not proper without a generic claim, and because all of the claims relate in some manner to taking pulse volume measurements. These are not found persuasive.

Regarding the applicant's interpretation of MPEP 806.04 and 37 CFR 1.146, the documents merely set forth the proper procedure for election of species requirements *if a generic claim is present*. The disclosed embodiments in the current application are independent and distinct.

Regarding the applicant's argument that the species are related by their use of pulse volume measurements, the disclosed embodiments are highly unrelated in their interpretation of pulse volume measurements, each requiring a separate field of search (see MPEP 808.02).

The requirement is still deemed proper and is therefore made FINAL.

2. Claims 1-23 and 28-55 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected species, there being no allowable generic or linking claim.

Applicant timely traversed the restriction (election) requirement in the reply filed on 13 July 2006.

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***Claim Rejections - 35 USC § 102***

3. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

4. Claim 24 is rejected under 35 U.S.C. 102(b) as being anticipated by Raines'232 (US Patent 5718232).

Raines'232 discloses a method for detecting peripheral vascular disease comprising taking quantitative pulse volume measurements from a plurality of positions on a patient's limb (column 7, lines 45-48) and using the measurements to detect peripheral vascular disease (column 9, lines 43-44).

***Claim Rejections - 35 USC § 103***

5. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.

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4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

6. Claim 25 is rejected under 35 U.S.C. 103(a) as being unpatentable over Raines'232 in view of Marks'211 (US Patent 4548211).

Raines'232 discloses all the elements of the current invention, as applied to claim 24 above, except for the detection of peripheral vascular disease comprising calculating a peak net inflow, an area under a pulse volume curve, or a pulse volume x heart rate product for the patient's limbs.

Marks'211 teaches a device that uses pulse volume measurements comprising calculation of peak net inflow (column 6, lines 31-34), in order to evaluate the health of a patient's peripheral vessels.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to have made the method of Raines'232 and calculated peak net inflow as part of the detection of peripheral vascular disease, as taught by Marks'211, in order to evaluate the health of the patient's peripheral vessels.

7. Claim 26 is rejected under 35 U.S.C. 103(a) as being unpatentable over Raines'232 in view of Raines'587 (US Patent 6149587).

Raines'232 discloses all the elements of the current invention, as applied to claim 24 above, except for the steps of the method being performed both before and after peripheral vascular disease treatment in order to determine whether the peripheral vascular disease has returned

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Raines'587 teaches a method of detecting peripheral vascular disease using pulse volume measurements wherein the measurements may be taken at different times and compared (column 6, lines 14-18) in order to determine the disease's current status (column 6, lines 1-3), so that the patient's health status is up to date.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to have made the method of Raines'232 and measured the patient's peripheral vascular disease status both before and after treatment to determine if recurrence occurs, as taught by Raines'587, so that the patient's health status is up to date.

8. Claim 27 is rejected under 35 U.S.C. 103(a) as being unpatentable over Raines'232 in view of Huizenga'614 (US Patent Application Publication 2004/0043614).

Raines'232 discloses all the elements of the current invention, as applied to claim 24 above, except for the method being performed both before and after peripheral vascular disease treatment in order to determine the efficacy of the treatment.

Huizenga'614 teaches a method of detection of peripheral vascular disease where the vascular disease detection is performed both before and after treatment in order to determine the efficacy of the treatment (paragraphs [0023] and [0047]), so that a health care provider can determine if an alternate treatment is needed.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to have made the method of Raines'232 and measured the patient's vascular disease status both before and after treatment to determine the

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treatment's efficacy, as taught by Huizenga'614, so that a health care provider can determine if an alternate treatment is needed.

### ***Conclusion***

9. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

US Patent 5715828 to Raines, which discloses a similar method of peripheral vascular disease detection

US Patent 5241963 to Shankar, which discloses a similar method of peripheral vascular disease detection

AHA Scientific Statement: Diagnosis and Treatment Chronic Arterial Insufficiency of the Lower Extremities: A Critical Review (Weitz et al.) Circulation: 94(11), 1996; 3026-3049.

US Patent 3796213 to Stephens, which discloses a similar method of peripheral vascular disease detection

10. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Karen E. Toth whose telephone number is 571-272-6824. The examiner can normally be reached on Monday through Friday.


If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Charles Marmor, II can be reached on 571-272-4730. The fax phone

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number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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**ROBERT L. NASSER**  
**PRIMARY EXAMINER**